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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/511,026
Filing Date: May 31, 2005
Appellant(s): HEDDING-ECKERICH, MONIKA

Gregory Turocy
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 10, 2008 appealing from the Office action mailed February 25, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner.

The rejection of claims 2, 10-12 and 15-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of applicant's arguments set forth in the Brief filed on December 10, 2008.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Connolly et al. TIPS (1999), Vol. 20, pages 218-225.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connolly et al. TIPS (1999), Vol. 20, pages 218-225 (Connolly).

Claims 1-6 and 10-16 are drawn to a method of using UMP or CMP for the treatment of affections of the peripheral nervous system and/or for the stimulation of the regeneration of nerves comprising administering UMP or CMP to a patient in need thereof. Claims 7-9 and 17 are drawn to a pharmaceutical composition consisting of UMP or CMP.

Connolly teaches that there are many disorders of pyrimidine metabolism and those that involve an alteration in uridine metabolism have neurological and system

effects, which provide insights into the biological activity of uridine and its analogues (page 218). An understanding of how uridine and its nucleotides modulate such vastly complicated biological systems should ultimately lead to the development of new ways for modulating human physiology in both normal and diseased states. Likely targets of therapy include the respiratory, circulatory, reproductive, and nervous systems, and the treatment of cancer and HIV infection.

Pyrimidines, related to purines, can be synthesized de novo within mammals. The ring structure is assembled through a multi-step pathway from simple precursors to make the base orotic acid, which is then converted by a multifunctional enzyme, uridine monophosphate (UMP) synthetase, to the nucleotide UMP. Further steps in the anabolic pathway result in the formation of the full complement of pyrimidine nucleotides and nucleic acid components from UMP. See Fig. 1. Uridine nucleotides can be catabolized by ectonucletidases, present on a variety of tissues and cells, including epithelial, endothelial, and neuronal tissues and astrocytes. For example, on rat superior cervical ganglia, ectonucleotidases degrade UTP to UDP, UMP and uridine. A mechanism also exists to reconvert UDP to UTP via an ectonucleoside diphosphokinase.

The few studies of the effects of uridine and uridine nucleotides on the isolated tissues from the nervous system have concentrated mostly on the peripheral nervous system and indicate that both uridine and its nucleotides have direct actions on and are capable of modulating peripheral nervous system activity (page 221). Clinically, uridine dramatically promoted recovery from the neural degeneration produced by diabetic

neuropathy (page 224). These actions of uridine developed over a prolonged period and thus might reflect changes in the metabolism of the patient, either directly within the nerves themselves, or at some other site. Even so, these studies illustrate that uridine can counteract certain pathological disorders and, along with its derivatives, is potentially useful in treating some neurodegenerative disorders.

Connolly differs from the instantly claimed invention in that Connolly teaches the therapeutic benefits of uridine and its nucleotides broadly; however, Connolly explicitly contemplates the use of “uridine” for treating diabetic neuropathy as set forth supra. The term "uridine", as used in the clinical trials shown in Table 1, is interpreted to embrace uridine and its nucleotides. Since this group represents a small number of compounds (uridine, UMP, UDP and UTP), the use of UMP would have been readily envisioned by one of ordinary skill in the art. As illustrated in Fig. 1, UMP, UDP and UTP (nucleotides) are produced from uridine (nucleoside) within mammals. See also page 218.

(10) Response to Argument

Applicant argues that Connolly at most implicate a role for nucleotides as neurotransmitters, but do not suggest a particular mechanism of action or implicate a role of claimed molecules in neuroregeneration. Applicant argues that Connolly fails to teach or suggest stimulating regeneration by synthesis of membrane phospholipids. On page 6 of the Brief applicant argues, “Connolly asserts, in light of Gallai et al, that uridine dramatically promoted the recovery from the neural regeneration produced by

diabetic neuropathy. This was an electrophysiological study that alleged improvement of motor and sensory responses in a small sample size (n=20) receiving treatment after 60, 120, and 180 day intervals…Although the amplitudes of motor and sensory responses appeared improved in individuals that received UMP…such assertions are suspect at best over shoddy experimental design, mainly small sample sizes."

Applicant's arguments have been fully considered but are not persuasive. The examiner would like to direct applicant's attention to Table 1 wherein Connolly proposes a mechanism of action by "↑ Lipid metabolism, via conversion of uridine cytidine nucleotides conjugates of ethanolamine and phospholipids". However, even if Connolly did not disclose such a mechanism, it should be noted that there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference. Applicant concedes that Connolly teaches administering UMP to patients suffering from diabetic neuropathy wherein the patient experienced a positive therapeutic response. In construing process claims and references, it is the identity of manipulative operations which leads to finding of unpatentability. In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

In regards to applicant's argument of "shoddy experimental design", when the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of

operability. No such facts have been provided by applicant. Applicant's argument in regards to the Wattig reference has been noted but is insufficient to overcome the instant rejection.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Patrick T. Lewis/

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